November 22, 2005

Katherine Uhl, MD
Director, Office of Women's Health
Food and Drug Administration
5600 Fishers Lane
Parklawn Building, Room 16-65
Rockville, MD 20857

RE: Docket Number 2005P-0411

Dear Dr. Uhl:

Congratulations on your new position with the Office of Women's Health! I know I join many colleagues in the women's health community in welcoming you to the Office and look forward to meeting you soon. The Jacobs Institute of Women's Health works to continuously improve the health care of women across their lifespan and in all populations. We have long been involved in educating women about hormone therapy and menopause, and advocating for the appropriate use of these important treatments. Most recently, the Jacobs Institute joined with the Food and Drug Administration (FDA) and the women's health community in the development of the agency's *Menopause and Hormones* information campaign. In this campaign and elsewhere, the Agency has stressed that all hormone therapies should be assumed to carry similar risks and benefits. For this reason, we do not understand why the FDA has allowed some compounding pharmacies to make misleading and unsubstantiated claims about the superiority of their bio-identical hormone products.

The Jacobs Institute joins our colleagues in the women's health and medical professional communities in calling upon the FDA to investigate the mass marketing and distribution of compounded bio-identical hormones to women. While compounded drugs are typically custom-mixed to meet the specific needs of an individual patient, certain compounding pharmacies appear to be manufacturing bio-identical hormones on a grand scale, rather than at the individual level. If specific compounding pharmacies' activities rise to the level of drug manufacturing, then they should be subject to the full range of FDA regulation.

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The Jacobs Institute believes that there are real safety and effectiveness concerns surrounding the use of these products. We are alarmed at the findings of FDA's 2001 survey of compounded drug products. This limited survey tested 29 products that could be ordered over the Internet, including compounded hormone products. The survey found that 34% (10 out of 29) "failed one or more standard quality tests," and "nine out of the 10 products with failing analytical results failed. . . potency testing." If BHRT products proved to be ineffective in preventing the "silent" disease osteoporosis, then that fact would not be known for years, by which time the bone loss will likely be irreversible.

The potential risks of compounded bio-identical hormones should not be borne by women who choose to use these products erroneously believing that they are superior to FDA-approved hormone therapies. The Jacobs Institute urges the FDA to be proactive in addressing this problem.

Sincerely,

Diane James, CAE
Executive Director

Cc: Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
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